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TOMTEC
IMAGING SYSTEMS

Jan 09th, 2008

Traditional 510(k) Summary

MAY 22 2009

Image-Arena 4.0 and Image-Arena Applications

4D Echo-Com 4.0
4D Image-Com 4.0
2D Cardiac Performance Analysis 1.0

Owner's Name and Address
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Common, Classification & Proprietary Names

Common Name: Various ultrasound Image Analysis System Software

Classification Name: Picture archiving and communications system

Proprietary Name(s): **Image-Arena 4.0 and Image-Arena Applications**
4D Echo-Com 4.0
4D Image-Com 4.0
2D Cardiac Performance Analysis 1.0

Predicate Devices:

Predicate Device 1: K083348 Image-Arena Applications (Image-Arena Platform 4.0/ Server Manager 4.0/ Echo-Com 4.0/ Image-Com 4.0), TomTec
Predicate Device 2: K072090 Siemens Diagnostic Ultrasound System, (only Velocity Vector Imaging = VVI component)

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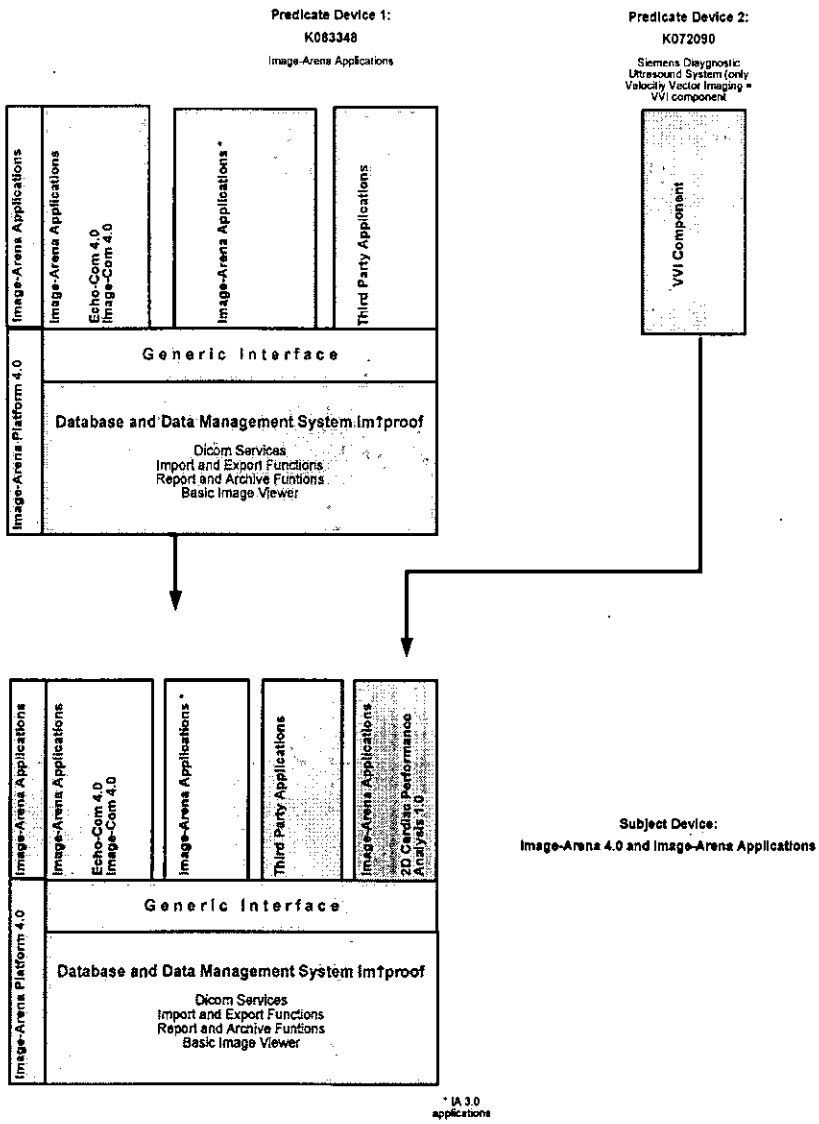
The Subject Device "Image-Arena 4.0 and Image Arena Applications" is a combination of Predicate Device 1: K083348 Image-Arena Applications (Image-Arena Platform 4.0/ Server Manager 4.0/ Echo-Com 4.0/ Image-Com 4.0), TomTec and Predicate Device 2: K072090 Siemens Diagnostic Ultrasound System, (only Velocity Vector Imaging = VVI-component).



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Device Description

The hardware requirements are based on an Intel Pentium high performance computer system and Microsoft® Windows XP Professional™ or Microsoft® Vista™ Operating System standards.

Image-Arena is suited as stand-alone workstation as well as networked multi-system installations. Image Arena is developed as a common interface platform for TomTec and 3rd party clinical application packages that can be connected to Image-Arena through the 3rd party Interface. The different application packages have all access to the central database and can be enabled on a modular basis thus allowing custom tailored solutions of Image-Arena.

The Image-Arena Application is a software tool package designed for analysis, documentation and archiving of ultrasound studies in multiple dimensions and X-ray angiography studies.

The Image-Arena Application software tools are modular structured and consist of different software modules.The different modules can be combined on the demand of the users to fulfil the requirements of a clinical researcher or routine oriented physician.

The Image-Arena Application offers features to import different digital 2D, 3D and 4D (dynamic 3D) image formats based on defined file format standards (DICOM-, HPSONOS-, GE-,TomTec- file formats) in one system, thus making image analysis independent of the ultrasound-device or other imaging devices used.

Offline measurements, documentation in standard report forms, the possibility to implement user-defined report templates and instant access to the stored data through digital archiving make it a flexible tool for image analysis and storage of different imaging modalities data including 2D, M-Mode, Pulsed (PW) Doppler Mode, Continuous (CW) wave Doppler Mode, Power Amplitude Doppler Mode, Color Doppler Mode, Doppler Tissue Imaging and 3D/4D imaging modes.

2D Cardiac Performance Analysis 1.0 is an additional clinical application package for high performance PC platforms based on Microsoft Windows™ operating system standards. 2D Cardiac Performance Analysis 1.0 is a software for the analysis, storage and retrieval of digitized ultrasound B-mode images. The data can be acquired by ultrasound machines that are able to acquire and store 2D ultrasound datasets. The digital 2D data can be used for comprehensive functional assessment of the myocardial function.

2D Cardiac Performance Analysis 1.0 is designed to run with a TomTec Data Management Platform for offline analysis. The TomTec Data Management Platform enhances the workflow by providing the database, import, export and

other advanced high-level research functionalities. All analyzed data and images will be transferred to the platform for reporting and statistical quantification purposes.

2D Cardiac Performance Analysis 1.0 is designed for the 2-dimensional functional analysis of myocardial function. Based on two dimensional datasets a speckle tracking algorithm supports the calculation of a 2D contour model that represents the endocardial and epicardial border. From that contours the corresponding velocities, displacement and strain can be derived.

The 2D Cardiac Performance Analysis 1.0 application is a visual and quantitative method for assessing cardiac mechanics and the dynamics of cardiac motion.

Intended Use

The Image-Arena software tool package is intended to retrieve, store, analyze and report digital ultrasound and XA studies. The Image-Arena platform is based on a SQL – database and is intended as an image management system for images of the modalities US and XA.

The Image-Arena software can import certain digital 2D or 3D image file formats of the modalities US and XA.

The software is suited for stand-alone workstations as well as for networked multi-system installations and therefore is an image management system for research and routine use in both physician practices and hospitals. It is intended as a general purpose digital medical image processing tool for cardiology.

2D Cardiac Performance Analysis 1.0 software is intended for quantification of the myocardial deformation (strain) and movement (displacement / velocity) for 2D echocardiographic data. Possible quantification results are velocity, displacement, strain, time-to-peak and phase.

Prerequisite is to draw a contour (endocard or endocard and epicard) in a 2D dataset. Based on this manual drawn contour, the SW calculates with a tracking algorithm the borders' displacement.

Technological Characteristics Comparison

For detailed comparison of all software functionalities of the subject device and the predicate devices refer to Chapt.12: Substantial Equivalent discussion.

Discussion according non-clinical performance data testing

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Testing was performed according to internal company procedures. Software testing and validation were done at the module and system level according to written test protocols established before testing was conducted. Test results were reviewed by designated technical professionals before software proceeded to release. Please refer to Chapter 16: Software, Verification and Validation Documentation.

Discussion according clinical performance data testing

The overall product concept was clinically accepted and the clinical test results support the conclusion that the subject device is as safe as effective, and performs as well as the predicate devices. Please refer to Chapter 16: Software, Verification and Validation Documentation.

Test Conclusions of non-clinical and clinical performance data

Test results support the conclusion, that the subject device is as safe as effective, and performs as well as or better than the predicate devices. Please refer to Chapter 16: Software, Verification and Validation Documentation.

Munich, Jan 09th, 2009

Inge Scheidt
QM & RA Officer

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 22 2009

TomTec Imaging Systems, GmbH
C/O Ms. Inge Scheidt
Edisonstrasse 6
Unterschleissheim
Germany D-85716

Re: K090461
Trade/Device Name: Image-Arena 4.0 and Image-Arena Applications
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture Archiving and Communications System
Regulatory Class: Class II
Product Codes: LLZ, DQK
Dated: May 11, 2009
Received: May 12, 2009

Dear Ms. Scheidt:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K090461

Device Name:

Image-Arena 4.0 and Image-Arena Applications
Echo-Com 4.0
Image-Com 4.0
2D Cardiac Performance Analysis 1.0

Indications for Use:

The Image-Arena Platform Software is intended to serve as a data management platform for clinical application packages. It provides information that is used for clinical diagnosis purposes.

The software is suited for stand-alone workstations as well as for networked multi-system installations and therefore is an image management system for research and routine use in both physician practices and hospitals. It is intended as a general purpose digital medical image processing tool for cardiology.

As the Image-Arena Applications software tool package is modular structured, clinical applications packages with different indications for use can be connected.

Echo-Com software is intended to serve as a versatile solution for Stress Echo examinations in patients who may not be receiving enough blood or oxygen because of blocked arteries.

Image-Com software is intended for reviewing, measuring and reporting of DICOM data of the cardiac modalities US and XA. It can be driven by Image-Arena or other third party platforms and is intended to launch other clinical applications.

The clinical application package 2D Cardiac Performance Analysis is indicated for cardiac quantification based on echocardiographic data. It provides measurements of myocardial function (displacement, velocity and strain) that is used for clinical diagnosis purposes of patients with suspected heart disease.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K090461